

**REMARKS****I. Status of the Claims and Formal Matters**

Claims 1-7, 9-15, 17-25, and 28 are presently pending in this application. Claims 21 and 22 are withdrawn from consideration. Claims 1, 12, 17, and 28 are amended. Claim 16 is cancelled.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendment of the claims, as presented herein, is not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, this amendment is made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendment should not give rise to any estoppel.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the changes place the application in condition for allowance.

**II. The Rejections Under 35 U.S.C. § 102(b) Are Overcome**

Claims 1, 3-4, 6-7, 9-11, 23, and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Oz (WO 91/04073). Applicants respectfully traverse this rejection.

To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Claims 1, 12, and 28 have been amended to specify applying electromagnetic energy “at an irradiance less than 3.5 W/cm<sup>2</sup>”. Support for this amendment can be found, for example, on page 5, lines 1-2 and in former claim 16 of the specification. Use of an irradiance less than 3.5 W/cm<sup>2</sup> is neither disclosed nor suggested in Oz. In fact, throughout Oz, the use of an irradiance higher than 3.5 W/cm<sup>2</sup> is described. The minimum irradiance Oz discloses is 3.8 W/cm<sup>2</sup>, and the majority of Oz teaches a higher irradiance (for example, 4.8 W/cm<sup>2</sup> (page 9, lines 24-25 and page 11, lines 25-26 of WO 91/04073), 5.66 to 12.04 W/cm<sup>2</sup> (page 15, lines 26-27), 7.6 W/cm<sup>2</sup> (page 17, line 1), and 9.6 W/cm<sup>2</sup> (page 24, lines 13-14)). Thus, it is respectfully submitted that the present invention is not anticipated by Oz.

Claims 3-4, 6-7, 9-11, and 23 depend from claim 1. Having established the novelty of claim 1, claims 3-4, 6-7, 9-11, and 23 are, by extension, also novel.

Reconsideration and withdrawal of the rejections of claims 1, 3-4, 6-7, 9-11, 23, and 28 under 35 U.S.C. § 102(b) is respectfully requested.

**III. The Rejections Under 35 U.S.C. § 103(a) Are Overcome**

Claims 2, 5, 12-20, and 24-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oz (WO 91/04073) in view of Khadem (5,552,452). Specifically, it is stated in the pending Office Action that “It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of the use of laser and dyes for refractive surgery, as taught by Khadem et al., to the method as per Oz...”

Claims 1, 12, and 17 have been amended to specify applying electromagnetic energy “at an irradiance less than 3.5 W/cm<sup>2</sup>”. As mentioned above, Oz neither discloses nor suggests using an irradiance less than 3.5 W/cm<sup>2</sup>. Furthermore, Oz explicitly states that the method acts by “...imparting energy absorbable by the energy absorbing material

in an amount sufficient and under conditions so as to cause heating of the tissue and welding of the tissue.” (emphasis added) This requirement that the tissue is heated in order to effect welding is reiterated on page 28, lines 5-7 of WO 91/04073, which states that “...the energy imparted to the energy absorbing material should be sufficient to effect heating of the tissue to result in welding.” Hence, Oz requires using an irradiance sufficient to heat the tissue.

In contrast, the present invention relates to effecting photochemical tissue bonding to form a tissue-tissue seal, rather than thermal welding, as described in the art. As stated on page 8, lines 21-22 of the present specification, the photoactivation “...involves insubstantial transfer of absorbed energy into heat energy.” Furthermore, as discussed on page 20, lines 14-23, the results in Example 6 indicate that a photochemical mechanism operates when lower irradiances are used, whereas a thermal mechanism operates at the highest irradiance tested (i.e., 3.8 W/cm<sup>2</sup>). This difference in mechanism is significant, because thermal damage was consistently observed when the irradiance was carried out at 3.82 W/cm<sup>2</sup>, as seen in Example 2 (page 17, line 27 to page 18, line 2) of the present specification. Furthermore, page 18, lines 2-4 state that “Thermal effects produced using high irradiances may produce collagen contraction resulting in distortion of the patient’s vision.”

Not only does Oz fail to disclose or suggest using an irradiance less than 3.5 W/cm<sup>2</sup>, but its fundamental requirement to effect heating of the tissue to result in welding effectively teaches away from the present invention, since the lower irradiances required by the present invention minimize any heating of the tissue.

For a rejection under 35 U.S.C. § 103 to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not in Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). There must also be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q.2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993).

As mentioned above, no motivation is provided in Oz—neither an explicit nor an implicit suggestion—to apply electromagnetic energy at an irradiance less than 3.5 W/cm<sup>2</sup>. The combination of Khadem with Oz does nothing to cure this defect. The

person of ordinary skill in the art would not be inclined to modify the teachings of Oz and Khadem, i.e., to apply electromagnetic energy at an irradiance less than  $3.5 \text{ W/cm}^2$ .

It is further stated in the pending Office Action that "It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum ranges of energy doses and irradiances, to a method for adhering tissue as per Khadem et al., in order to minimize tissue damage." As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Like Oz, Khadem fails to state (either explicitly or implicitly) the significance of the irradiance of the electromagnetic energy to be imparted. Therefore, the desirability of apply electromagnetic energy at an irradiance of less than  $3.5 \text{ W/cm}^2$  is lacking in this combination of references.

Certainly, the person of ordinary skill in the art did not have a reasonable expectation of success for a method of tissue repair that was both non-thermal and substrate-free, as claimed, in view of the combination of Oz and Khadem. The principal teachings of Khadem require a protein solder for sufficient bonding strength (for example, column 9, lines 39-43, column 10, lines 54-67, Table 2, column 12, lines 17-21, and Examples I through VIII). At the same time, the teachings of Oz require heating of the tissue (for example, abstract, page 3, lines 3-11, page 6, lines 4-12) and describe an irradiance of at least  $3.8 \text{ J/cm}^2$  (as already iterated above). The combination of the two documents does not provide the skilled person with any reasonable expectation of success based upon simply varying parameters for the sake of routine optimization. In fact, Khadem specifically directs its efforts towards optimizing bond strength by varying the dye-protein combination, while Oz describes the enhancement of "weld strength" based on mixing exogenous dye with fibrinogen prior to application (page 6, lines 4-12). The skilled person is not left with any motivation to vary the parameters employed in the tissue repair methods of Khadem and Oz, much less any reasonable expectation of success in achieving sufficient bonding strength upon variation to non-thermal and substrate-free methods.

If an independent claim is non-obvious under 35 U.S.C. § 103, then any claim depending therefrom is non-obvious. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Claims 2, 5, and 24-25 depend from claim 1. Claims 13-16 depend from claim 12. Claims 18-20 depend from claim 17. Having established the non-obviousness of claims 1, 12, and 17, claims 2, 5, 13-16, 18-20, and 24-25 are, by extension, also non-obvious.

**REQUEST FOR AN INTERVIEW**

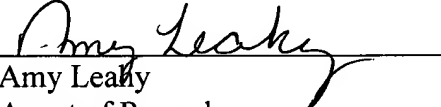
If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested; and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application, reconsideration, and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

Respectfully submitted,

Dated  
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